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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,791	08/08/2001	David Hung	12.019011	9920

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EXAMINER

WINKLER, ULRIKE

ART UNIT PAPER NUMBER

1648

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/923,791

Applicant(s)

HUNG, DAVID

Examiner

Ulrike Winkler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/26/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-15 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-15 and 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The Amendment filed March 9, 2004) in response to the Office Action of September 9, 2003 is acknowledged and has been entered. Claims 1, 2, 5-15, 17-20 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 103

The rejection of claims 1, 2, 5-15, 17-20 under 35 U.S.C. 103(a) as being unpatentable over Evron et al. (Lancet, April 28, 2001) in view of Sukumar et al. (U.S. Pat. No. 5,763,415), Makita et al. (Breast Cancer Research, 1991, IDS), King et al. (JNCI, 1983, IDS), Noguchi et al. (American Journal of Pathology 1994), Gross G. (Intervirology 1997) and Androphy (Ciba Found. Symposium, 1986) is **withdrawn** because the Evron et al. reference was published after the earliest priority date of the instant invention.

Claims 1, 2, 5-15, 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Love et al. (U.S.Pat. No. 6,221,622, IDS) and Makita et al. (Breast Cancer Research, 1991, IDS) in view of Sukumar et al. (U.S. Pat. No. 5,763,415), King et al. (JNCI, 1983, IDS), Noguchi et al. (American Journal of Pathology 1994), Gross G. (Intervirology 1997) and Androphy (Ciba Found. Symposium, 1986). This rejection reinstates the prior 35 U.S.C. 103(a) rejection.

The instant invention is drawn to a method comprising the steps of obtaining fluid and washing fluid from a single breast duct and analyzing the sample for the presence of a viral

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agent. The viral agent is identified with a viral marker (whole virus, protein or nucleic acid).

The invention further comprises treating a patient at risk by administering an antiviral agent.

The antiviral agent can be administered through catheter to the breast duct or the agent can be administered systemically.

A recitation of the intended use “identifying a patient at risk of developing breast cancer or pre-cancer” of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The term “identifying a patient at risk of developing breast cancer or pre-cancer” is being viewed as an intended use which confers no further substance to the claim and is given little patentable weight (see *In re Pearson*, 494 F.2nd 1399, 1403, 181 USPQ 641, 664 (CCPA 1974)).

Love (U.S. Pat. No. 6,221,622, IDS) teaches a method of obtaining cellular material from a single breast duct using a double lumen catheter that allows for the simultaneous insertion and withdrawal of fluid from a single duct. The duct washing is used for diagnostics an evaluation can be made on a duct-by-duct basis (see summary of invention). The epithelial cells, other cells and non cellular material obtained by this method can be examined morphologically, histochemically and immunohistochemically for cancer or pre-cancer conditions present in the lining of the duct, non-cellular material released into duct can also be examined (see column 3, lines 39-46, and claims). The reference teaches the ability to irrigate (introduce fluid) and wash

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(remove fluid) from a single breast duct and using the martial for the analyses of precursor cancer markers. The reference teaches that ducts may be washed multiple times. In addition the reference suggest that treatment can be targeted to an effected duct (column 1, line 53-56). The reference does not specifically teach detecting a viral agent, the reference uses terms such as cancer or pre-cancer conditions. This broad category encompasses viral agents, which are known to be involved in the cancer pathology.

Applicant's response to the prior rejection using the Love et al. reference was that the Love et al. reference was directed to using a double lumen catheter, while the claims now are draw to an access tool comprising an "elongated lumen." The prior claim amendment removed the phrasing "at least one" from modifying the elongated lumen and applicants' arguments were directed that the instantly claimed elongated lumen is a single lumen. However, the claim limitation "comprising an elongated lumen" does not narrow the claim a single lumen catheter. MPEP 2111.03 The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997). The Love et al. reference still applies even if the claims were limited to a single lumen catheter because the reference teaches the use of a syringe to wash the breast duct. The reference teaches that it was known to use a syringe for the purpose of introducing fluid and retrieving fluid from the breast duct (see column 2, lines 8-20). A reference may be considered for all that it fairly teaches see MPEP 2144.01 "[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to

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draw therefrom." *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968); *In re Boe*, 148 USPQ 507 (CCPA 1966). Although the Love et al. reference teaches that the use of a single lumen syringe was not ideal for the purpose of retrieving washing fluid from a breast duct, the reference teaches that the single lumen syringe is capable of introducing and removing fluid from a breast duct.

Makita et al. (Breast Cancer Research, 1991, IDS) teaches using duct endoscopy to obtain a biopsy sample from a single breast duct, followed by analyzing the sample to see if the contains a viral agent, such as papilloma (table 1). The procedure is to first insert a bougie to dilate the mammary duct (see Fig. 3), followed by inserting an outer cylinder with a rounded inner needle into the duct, the inner needle is removed and the endoscope is inserted. With the use of the endoscope the outer cylinder (a 16 gauge Surflo intravenous catheter; an elongated lumen) is moved to the location of a lesion. The endoscope is removed and a syringe is attached to the outer cylinder (an elongated lumen) and the sample including ductal fluid is aspirated into the outer cylinder. The reference establishes that at the time the invention was made it was known in the art that papillomavirus is present in the epithelial cells of the breast duct. The reference does not teach adding a washing fluid to the duct before retrieving the fluid and sample.

Sukumar et al. (U.S. Pat. No. 5,763,415) teaches the use of cannulation of the breast duct to introduce an epithelial cell destroying agent/vector into a breast duct at risk of developing solid tumors. The reference does not teach using a virus specific agent. The composition used by the reference destroys epithelial cells, which are the cells that are infected by papillomavirus. The reference acknowledges the advantage of treating a single duct, which will result in the

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preservation of the remainder of the breast tissue. The reference establishes that at the time the invention was made that it was known in the art to introduce a treatment agent into the breast duct.

King et al. (JNCI, 1983, IDS) teaches that fluid obtained from nipple aspirate can be used to assess the presence of a viral agent, papilloma and papillomatosis (see table 5). The reference obtains fluid from multiple ducts and not a single duct. The reference establishes that at the time the invention was made it was known in the art that papillomavirus can be detected in fluid samples obtained from breast ducts. The reference does not teach infusion of the breast duct with antiviral agents after discovering the presence of a viral agent.

Noguchi et al. teach using PCR analysis to determine the presence of papillomavirus in the breast duct. In this reference the samples were obtained from surgical samples and not from fluid extractions of the breast. The reference does teach the correlation between multiple intraductal papillomavirus lesions and pre-cancerous lesions (see discussion). The reference does establish that it was known in the art at the time the invention was made to use the sensitive PCR technique to detect papillomavirus in samples.

Androphy (Ciba Found. Symposium, 1986) teaches the use of interferon for the treatment of papillomavirus. Treatment may be giving intralesionally or systemically (see abstract). The reference established that it was known in the art at the time the invention was made to treat papillomavirus infection with an antiviral agent.

Gross G (Intervirology) teaches that interferon and other immunotherapies can be used to treat papillomavirus infection. The interferon may be administered systemically or topically or

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intralesionally (see page 370 column 1). The reference established that it was known in the art at the time the invention was made to treat papillomavirus infection with an antiviral agent.

The prior art establishes that it was known to introduce/extract washing fluids using a catheter. The prior art established that it was known to introduce therapeutic agents into the breast duct directly. It was also known in the prior art that papillomavirus lesions were found in the breast duct. Based on what was known in the prior art at the time the invention was made it would have been obvious to one of ordinary skill in the art to (1) utilize a duct washing system for the diagnosis of the presence of a viral agent in the breast duct and (2) utilize a duct washing system for the diagnosis of the presence of a viral agent followed by the introduction of an antiviral agent to the patient. One having ordinary skill in the art would have been motivated to use the fluid retrieval system of Love et al. which introduces a washing fluid into the breast duct and apply it the fluid retrieval and analysis taught in Makita et al. King et al. and Noguchi et al. each establish that the presence of papillomavirus in the epithelial layers of the breast duct was known in the art. Optimizing the diagnostic condition with repeated sample analysis would be an obvious step to the ordinary artisan. If the timing of the monitoring step provides an unexpected result, Applicant needs to point out what the unexpected results are. Applying a therapeutic antiviral agent to the breast duct would be obvious. Sukumar et al. teach the introduction of a composition into the breast duct, which destroys the epithelial tissue a primary site for papillomavirus infection. Androphy and Gross teach the use of interferon for the treatment of papillomavirus, the interferon can be administered directly to the papillomavirus lesion or it can be administered systemically. Optimizing the treatment condition would be an obvious step to the ordinary artisan. Therefore, taken what was known in the prior art as a whole

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it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to identify the presence of papillomavirus in a single breast duct and apply treatment to the single breast duct.

Claim Objections

Claim 5 is objected to because of the following informalities: The claim is dependent on a canceled claim. Appropriate correction is required.

Conclusion

No claims allowed.


Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.


ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER

12/23/04